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60 East 42nd, Street
New York, NY 10165

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,070,877

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,070,877, which claims the method of using the human drug product ADENOSCAN®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 159 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of January 2, 1996 (61 Fed. Reg. 73). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 \text{ (Testing Phase) + Approval Phase} \\ &= 1/2 (768 - 768) + 1,920 - 663 \\ &= 1,257 \text{ days}\end{aligned}$$

Since the entire testing phase occurred before the patent issued, none of the testing phase has been considered in the determination of the length of the regulatory review period. Furthermore, since the approval phase of the regulatory review period began February 14, 1990, before the patent issued (December 10, 1991), only that portion of the approval phase of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From February 14, 1990 to December 10, 1991 is 663 days; this period is subtracted for the number of days occurring in the approval phase according to the FDA determination of the length of the regulatory review period: $1,920 - 663 = 1,257$ days.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (May 18, 1995) when added to the period of extension calculated above (1,257 days) cannot exceed fourteen years. The period of extension is thus limited to May 18, 2009, by operation of 35 U.S.C. § 156(c)(3). Since the patent term of seventeen years (35 U.S.C. § 154) would expire on December 10, 2008, the period of extension is

the number of days to extend the term of the patent from its expiration date to and including May 18, 2009, or 159 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 159 days.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,070,877
Granted:	December 10, 1991
Original Expiration Date:	December 10, 2008
Applicant:	Syed M. Mohiuddin et al.
Owner of Record:	Medco Research Inc.
Title:	Novel Method of Myocardial Imaging
Classification:	128/653.4
Product Trade Name:	ADENOSCAN®
Term Extended:	159 days

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916

Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

Telephone inquiries related to this determination should be directed to Karin Tyson at (703) 306-3159.



Hiram H. Bernstein
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

(703) 305-9285

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: ADENOSCAN®
FDA Docket No.: 95E-0303